AF/1615

Docket No. MCP-281

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: BUNICK, et al.
Serial No.: 09/896,052
Filed: 06/29/2001
Title: BRITTLE COATING, SOFT CORE DOSAGE FORM

Art Unit : 1615
Examiner : Oh, Simon J.

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July 25, 2005
(Date of Deposit)

Timothy E. Tracy
(Name of applicant, assignee, or Registered Representative)

/Timothy E. Tracy, Reg. #39,401/
(Signature)

July 25, 2005
(Date of Signature)

Mail-Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**REPLY BRIEF**

Dear Sir:

In accordance with the provisions of 37 CFR § 41.41, this Reply Brief is timely filed with an executed Certificate of Mailing on or before July 25, 2005. (See 37 CFR §§ 1.7 and 1.8)

1) THE REJECTION DOES NOT ADDRESS THE CLAIMED INVENTION AS A WHOLE

The Examiner continues to ignore the fact the claimed subject matter is affirmatively directed to a **texture** masking oral dosage form. As disclosed in paragraph [0011] of the instant application, the grittiness of the active agent is masked. This is texture masking. The rejection focuses on taste masking and does not point to where texture masking specifically is disclosed or suggested in any of the cited documents.

It is respectfully submitted that taste masking does not always and inevitably provide texture masking. It is the Examiner's failure to address the invention as whole that leads to the Examiner's failure to consider the combination of claimed particle size of the active agent in the soft core and the claimed weight ratio of active agent particles to brittle shell in making out the rejection. Yet it is the combination of claimed particle size of the active agent in the soft core and the claimed weight ratio of active agent particles to brittle shell that help to provide the texture masking of the present invention. It is not seen where the rejection addresses the claim as whole based on the cited documents to any expectation of success for providing texture masking. For this reason, the rejection continues to be improper and should be withdrawn.

2) THE EXAMINER APPEARS TO MISUNDERSTAND FACTS

As is fundamental, a *prima facie* case of obviousness must be based on facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (C.C.P.A. 1970). When the rejection is not supported by facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (B.P.A.I. 1993).

The Examiner asserted that "[Friend] clearly states that the **drug particles** formedare sieved through an 840 μm screen [] which would place them within the preferred range particle size []." (Examiner's Answer at 6.) With all due respect, Friend actually discloses that "[t]he dried microcapsules [] were .... sieved through an 840 μm screen." (Friend at Column 11, lines 51-65.) It is not seen where "drug particles" are factually identical to "microcapsules." Therefore, it appears that the rejection is based on facts that are not in the record. For this additional reason, the rejection is improper and should be withdrawn.

Respectfully submitted,

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DATE: July 25, 2005